

REMARKS

By this Amendment, Applicant proposes canceling claims 4, 172, and 176 without prejudice or disclaimer of the subject matter contained therein. Accordingly, claims 1, 2, 5, 7, 120, 121, 124, 126, 127, 129-132, 134, 135, 137, 138, 140, 142-145, 147, 148, 150-155, 157, 164-167, 173-175, and 177-181 will be pending in this application upon entry of the proposed amendments. No new matter has been introduced by this Amendment.

Applicant requests that this Amendment After Final supersede the unentered Amendment After Final filed November 5, 2008.

In the final Office Action mailed September 9, 2008 ("Office Action"), claim 4 was rejected under 35 U.S.C. § 112, second paragraph; claims 1, 2, 5, 7, 120, 121, 124, 126, 127, 129-131, 134, 135, 137, 138, 140, 142-144, 147, 148, 150-154, 157, 164-167, 172, 174, 176, 178, 180, and 181 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 3,604,425 to Le Roy ("*Le Roy*") in view of U.S. Patent No. 5,620,452 to Yoon ("*Yoon*"); claims 132, 145, 155, 173, 175, 177, and 179 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Le Roy* in view of *Yoon* and further in view of U.S. Patent No. 3,032,039 to Beaty ("*Beaty*").

I. 35 U.S.C. § 112, Second Paragraph, Rejection

Claim 4 was rejected under 35 U.S.C. § 112, second paragraph. The Office Action alleges that the recitation of "an additional anchoring portion including a fixation hole configured to receive an anchoring member" in claim 4 contradicts the recitation of "the other of the first and second arms does not include a structure for receiving the

integral anchoring portion” in claim 1. (Office Action, p. 2, ll. 7-15). Applicant respectfully disagrees. However, in the interests of expediting prosecution, Applicant proposes canceling claim 4. Accordingly, the rejection of claim 4 under 35 U.S.C. § 112, second paragraph, is moot.

The Advisory Action mailed December 5, 2008 (“Advisory Action”) stated that the proposed amendment to claim 6 requires further consideration and/or search. (Advisory Action, p. 2, l. 1). Since dependent claim 4 was the only claim that was proposed to be amended in the Amendment After Final filed November 5, 2008, it is assumed that the Examiner intended to refer to claim 4. Since Applicant proposes canceling claim 4, further consideration and/or search is not required.

II. 35 U.S.C. § 103(a) Rejections

Applicant respectfully traverses the rejection of claims 1, 2, 5, 7, 120, 121, 124, 126, 127, 129-132, 134, 135, 137, 138, 140, 142-145, 147, 148, 150-155, 157, 164-167, 173-175, and 177-181 as being unpatentable under 35 U.S.C. § 103(a). The rejection is improper because the criteria for establishing a *prima facie* case of obviousness has not been met.

When evaluating claims for obviousness under 35 U.S.C. § 103, “[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art.” M.P.E.P. § 2143.03, internal citation omitted. Furthermore, “[a] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention.” M.P.E.P. § 2141.02(VI), internal citation omitted. It has long been held that a proposed modification of the prior art cannot render the prior art

“unsatisfactory for its intended purpose” or “change its principle of operation.” M.P.E.P. § 2143.01(V)-(VI). Moreover, it is improper to combine references where the references teach away from their combination. M.P.E.P. § 2145(X)(D).

A. There is no motivation to modify the clip of *Le Roy* to be comprised of bioabsorbable material capable of disintegrating in a body

Independent claim 1 recites a device for securing a fold of tissue in a medical procedure including, among other things, “a first arm [and] a second arm . . . wherein the first and second arms are comprised of a bioabsorbable material such that the first and second arms are capable of disintegrating in a body.”

Le Roy discloses a clip 10 including leg sections 24 “for use in clamping wound flaps to prevent the flow of blood from severed arteries, capillaries and the like.” (*Le Roy*, col. 1, ll. 11-13; col. 2, ll. 47-50; Figs. 1-5). The clip 10 of *Le Roy* includes projections 18 that are squeezed together using an applicator tool 14 or by hand to allow application and removal of the clip 10. (*Le Roy*, col. 2, ll. 64-69; and Fig. 1).

The Office Action acknowledges that *Le Roy* does not disclose that “the first and second arms are comprised of a bioabsorbable material such that the first and second arms are capable of disintegrating in a body,” as recited in claim 1. (Office Action, p. 5, ll. 1-2). However, the Office Action contends that *Yoon* discloses this feature and that “it would have been obvious to one of ordinary skill in the art . . . to manufacture the device of *Le Roy* with a bioabsorbable material since it would allow the clip to dissolve in the body without requiring an additional surgery for removal.” (Office Action, p. 5, ll. 3-7).

However, there is no motivation to modify the clip 10 of *Le Roy* to be comprised of bioabsorbable material, as proposed by the Office Action. *Le Roy* states that the “[c]lip 10 is particularly effective with scalp and back wounds, and . . . abdominal or long flap wounds as may be necessary in extremity work.” (*Le Roy*, col. 3, ll. 21-24). Therefore, *Le Roy* discloses using the clip 10 for external wounds on the patient’s skin, not in the patient’s body. Accordingly, since the clip 10 of *Le Roy* is for external purposes, there is no motivation to modify the clip 10 of *Le Roy* to be made of bioabsorbable material capable of disintegrating in a body.

Le Roy also states that the clip 10 “can be easily and rapidly removed either with applicator 14 or by hand.” (*Le Roy*, col. 2, ll. 64-65). *Le Roy* provides projections 18 on the clip 10 to allow the clip 10 to be removed manually. (*Le Roy*, col. 2, ll. 65-67). *Le Roy* states that the clip 10 is specifically designed to allow the clip 10 to be “easily and rapidly removed . . . off the wound flap 16 without noticeable damage to the tissue.” (*Le Roy*, col. 2, ll. 68-69). Therefore, since the clip 10 of *Le Roy* is specifically designed to be easily and rapidly removeable, there is no motivation to modify the clip 10 to allow it to disintegrate in the patient’s body, i.e., so that the clip 10 is not removed by, for example, a tool or hand. Accordingly, there is no motivation to modify the clip 10 of *Le Roy* to include arms that are “comprised of a bioabsorbable material such that the . . . arms are capable of disintegrating in a body,” as recited in claim 1.

In response to the above arguments, which were provided in the unentered Amendment After Final filed November 5, 2008, the Advisory Action pointed to a portion of *Le Roy* that states that the clip can be located if “lost” within the operative site. (Advisory Action, p. 2, ll. 7-8). The Advisory Action alleged that, since the clip of *Le Roy*

may be lost within the body, the clip may be used internally, and therefore, it would be obvious to modify the clip to be formed of a bioabsorbable material. (Advisory Action, p. 2, ll. 7-10).

Le Roy states that the clip may be "lost" in the operative site. (*Le Roy*, col. 3, ll. 10-12). The Advisory Action specifically alleged that "[a] clip used exclusively in external surfaces of the patient will not require such disclosure." (Advisory Action, p. 2, l. 8). Applicant respectfully disagrees, however, because *Le Roy* merely states that the clip may be introduced internally by accident. A clip used externally may be lost if the clip enters by accident through an external wound. This disclosure of *Le Roy* does not disclose or suggest using the clip internally. Rather, this disclosure of *Le Roy* further shows that the clip is not intended to be inside the patient's body and is intended to be located so that it may be removed from the patient's body. There is no motivation to modify the clip of *Le Roy* to be comprised of bioabsorbable material. Furthermore, as noted above, the clip of *Le Roy* is specifically designed to be easily and rapidly removeable by tool or by hand. Therefore, for this additional reason, there is no motivation to modify the clip of *Le Roy* to be comprised of bioabsorbable material.

Independent claims 120, 135, and 148, although of different scope, include elements corresponding to those of claim 1 discussed above. Thus, for the same reasons discussed above with regard to claim 1, claims 120, 135, and 148 are also patentable over *Le Roy* and *Yoon*. In addition, independent claims 120, 135, and 148 recite additional features that are neither taught nor suggested by the cited references and, therefore, each is also separately patentable.

Claims 2, 5, 7, 121, 124, 126, 127, 129-131, 134, 137, 138, 140, 142-144, 147, 150-154, 157, 164-167, 174, 178, 180, and 181 are also patentable over *Le Roy* and *Yoon* at least due to their dependence from one of claims 1, 120, 135, and 148. A *prima facie* case of obviousness has not been established with respect to the claims.

Applicant also respectfully traverses the rejection of claims 132, 145, 155, 173, 175, 177, and 179 under 35 U.S.C. § 103(a) as being unpatentable over *Le Roy* in view of *Yoon* and further in view of *Beaty*. Claims 132, 145, 155, 173, 175, 177, and 179 depend from one of independent claims 1, 120, 135, and 148. *Beaty* discloses an arterial and venous clamp including a strip of metal 2 that forms a pair of arms 6, 8 with reversely turned tips 14, 16. (*Beaty*, col. 2, ll. 6-9 and 22-23). However, *Beaty* does not cure the deficiencies of *Le Roy* and *Yoon* noted above with respect to independent claims 1, 120, 135, and 148, nor was it cited for such disclosure. Therefore, for at least the same reasons discussed above with regard to independent claims 1, 120, 135, and 148, claims 132, 145, 155, 173, 175, 177, and 179 are also patentable over *Le Roy*, *Yoon*, and *Beaty*.

In addition, for at least the reasons described below, claims 2, 5, 7, 121, 124, 126, 127, 129-132, 134, 137, 138, 140, 142-145, 147, 150-155, 157, 164-167, 173-175, and 177-181 recite unique combinations of features that are neither taught nor suggested by the cited references and, therefore, each is also separately patentable.

The Advisory Action did not address the following arguments provided in the Amendment After Final filed November 5, 2008 regarding several dependent claims, e.g., that modifying *Le Roy* based on *Beaty* is improper; that *Le Roy* and *Yoon* do not disclose or suggest the claimed pin, bolt, suture, staple, or rod; that *Le Roy* and *Yoon*

do not disclose or suggest the claimed tapering portion curving away from the gap; or that *Le Roy* and *Yoon* do not disclose or suggest the claimed barb configured to penetrate a surface of the fold of tissue.

B. Modifying *Le Roy* based on *Beaty* is improper (claims 132, 145, 155, 173, 175, 177, and 179)

As noted above, claims 132, 145, 155, 173, 175, 177, and 179, which depend from one of independent claims 1, 120, 135, and 148, were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Le Roy* in view of *Yoon* and further in view of *Beaty*. However, modifying *Le Roy* based on *Beaty*, as proposed by the Office Action, is improper for at least the following reasons.

The Office Action acknowledges that *Le Roy* does not disclose or suggest the “gripping tab located at the distal end of one of the first and second arms” recited in claims 132, 145, and 155 or the “crook for providing a surface to push against to bring the arms closer together during insertion” recited in claims 173, 175, 177, and 179.

(Office Action, p. 7, ll. 6-7). The Office Action contends that:

Le Roy discloses tabs located in the proximal [ends of the leg sections 24]. . . . [I]t would have been obvious . . . to modify the device of Le Roy to have the tabs be located on the distal end tabs because such arrangement is well known in the art. Furthermore, the arrangement taught by *Beaty* is an equivalent structure for manipulating a clip so one . . . would have found it obvious to substitute a tab on the distal end for the tab on the proximal end since it would yield predictable results (both allow manipulation of the clip). (Office Action, p. 7, ll. 8-18).

However, in this case, one of ordinary skill in the art would not have made the substitution proposed by the Office Action because the proposed substitution would

render the clip of *Le Roy* unsatisfactory for its intended purpose and would change its principle of operation.

Le Roy summarizes its invention as specific structure at the proximal end of the device to facilitate insertion of the wound flap in the device. Specifically, *Le Roy* states that “[w]hen force is applied to the projections [18] they act as levers to spread the longitudinal slit and facilitate the insertion of the wound flap therein.” (*Le Roy*, col. 1, ll. 38-40). *Le Roy* also states that the clip 10 “can be easily and rapidly removed either with applicator 14 or by hand” and that the projections 18 can be squeezed together and act as levers to spread the flanges 28 away from each other, thereby allowing for manual removal of the clip 10. (*Le Roy*, col. 2, ll. 64-67; Fig. 1). Therefore, the intended purpose of *Le Roy*, and the primary focus of its invention, is to include the projections 18 at the proximal end and to allow the projections 18 to be squeezed together so that they act as levers that spread the flanges 28 apart.

Modifying the clip 10 of *Le Roy* to substitute the reversely turned tips 14, 16 located on the distal ends of the arms of *Beaty* for the proximally-located projections 18 of *Le Roy* would render the clip 10 unsatisfactory for its intended purpose and would change its principle of operation. The tips 14, 16 of *Beaty* at the distal ends cannot be squeezed together as levers to spread the flanges of the clip apart. Instead, since the tips 14, 16 are located at the distal ends of the arms, the tips 14, 16 would close the clip if squeezed together.

Also, the applicator 14 shown in Fig. 1 of *Le Roy* is only capable of squeezing together two parts, e.g., the projections 18 of *Le Roy* or the tips 14, 16 of *Beaty*. If the clip were modified as proposed by the Office Action, the applicator 14 would merely

squeeze the tips 14, 16 together. If the tips 14, 16 of *Beaty* at the distal ends are squeezed together, the flanges of the clip would be forced toward each other to close the clip. Therefore, the applicator 14 of *Le Roy* is incapable of opening the modified clip using the tips 14, 16 of *Beaty*. Since the projections 18 of *Le Roy* are intended to be used to open the clip, the proposed modification renders the clip unsatisfactory for its intended purpose and changes its principle of operation.

Accordingly, the Office Action has not provided sufficient findings to support a conclusion that claims 132, 145, 155, 173, 175, 177, and 179 would be obvious. Accordingly, claims 132, 145, 155, 173, 175, 177, and 179 are patentable over *Le Roy*, *Yoon*, and *Beaty*.

C. *Le Roy* and *Yoon* do not disclose or suggest the claimed pin, bolt, suture, staple, or rod (claims 129 and 142)

Claim 129, which depends from independent claim 120, recites “an additional anchoring portion including one of a pin, bolt, suture, staple, and rod configured to pierce the tissue fold.” Claim 142, which depends from independent claim 135, recites similar features. The Office Action contends that the leg sections 24 of *Le Roy* correspond to the claimed additional anchoring portion, and that the leg sections 24 have “a tip that can be called a pin that is capable of piercing tissues.” (Office Action, p. 6, ll. 19-20). However, Applicant disagrees since *Le Roy* states that the leg sections 24 “terminate in flanges 28 . . . [with] parallel undulations 30,” as shown in Figs. 4 and 5, “with blunt or rounded ends 34.” (*Le Roy*, col. 2, ll. 50-60). The sinusoidal undulations 30 of *Le Roy* do not form tips or pins and are not capable of

piercing tissue, contrary to the Office Action's assertion. Rather, *Le Roy* states that the configuration "minimiz[es] any pain [to the wound flap] or undue damage to the tissue." (*Le Roy*, col. 2, ll. 60-63). *Yoon* does not cure the deficiencies of *Le Roy* noted above, nor was it cited for such disclosure. Accordingly, claims 129 and 142 are patentable over *Le Roy* and *Yoon*.

D. *Le Roy* and *Yoon* do not disclose or suggest the claimed tapering portion curving away from the gap (claims 130, 143, 153)

Claims 130, 143, and 153, which depend from independent claims 120, 135, and 148, recite that "the distal end of one of the first and second arms includes a tapering portion curving away from the gap." The Office Action appears to contend that *Le Roy* teaches this feature. (Office Action, p. 6, ll. 21-22). The leg sections 24 of *Le Roy*, which the Office Action contends correspond to the claimed arms, include the flanges 28 that are bent inward into the space between the leg sections 24, as shown in Fig. 3 and 5. The flanges 28 of *Le Roy* are curved into the slit 12 separating the flanges 28 so that the flanges 28 taper toward the slit 12. (*Le Roy*, col. 2, ll. 56-60 and Fig. 5). Therefore, even if one were to assume that the leg sections 24 of *Le Roy* correspond to the claimed arms with tapering portions, which Applicant does not concede, *Le Roy* does not disclose that such tapering portions "curv[e] away from the gap," as recited in claims 130, 143, and 153. (Emphasis added). *Yoon* does not cure the deficiencies of *Le Roy* noted above, nor was it cited for such disclosure. Accordingly, claims 130, 143, and 153 are patentable over *Le Roy* and *Yoon*.

E. *Le Roy* and *Yoon* do not disclose or suggest the claimed barb configured to penetrate a surface of the fold of tissue (claims 174 and 178)

Claim 174, which depends from independent claim 120, recites that “the anchoring portion includes at least a portion in the shape of a barb configured to penetrate a surface of the fold of tissue.” Claim 178, which depends from independent claim 148, recites similar features. The Office Action contends that the flanges 28 of *Le Roy* correspond to the claimed anchoring portion configured to penetrate a surface of the fold of tissue. However, as noted above, the sinusoidal undulations 30 of *Le Roy* formed at the ends of the flanges 28 are not capable of piercing tissue, contrary to the Office Action’s assertion. *Yoon* does not cure the deficiencies of *Le Roy* noted above, nor was it cited for such disclosure. Accordingly, claims 174 and 178 are patentable over *Le Roy* and *Yoon*.

III. Conclusion

Accordingly, Applicant respectfully submits that all pending claims are in condition for allowance. Applicant respectfully requests entry of this Amendment, reconsideration and reexamination of the application, and timely allowance of the pending claims.

Applicant respectfully requests that this Amendment under 37 C.F.R. § 1.116 be entered by the Examiner and that this application be allowed.

Applicant also submits that the entry of the amendments would place the application in better form for appeal, should the Examiner dispute the patentability of the pending claims.

In discussing the specification, claims, and drawings in this Amendment After Final, it is to be understood that Applicant is in no way intending to limit the scope of the claims to an exemplary embodiment described in the specification or abstract and/or shown in the drawings. Rather, Applicant is entitled to have the claims interpreted broadly, to the maximum extent permitted by statute, regulation, and applicable case law.

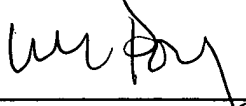
If the Examiner believes a telephone conversation might advance prosecution, the Examiner is cordially invited to call Applicant's undersigned representative at 202-408-4129.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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